

Amendments to the Claims:

Claim 104 is currently amended. This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. A method for introducing one or more substances into an intervertebral disc, the method comprising:
positioning a distal portion of a catheter device in the disc;
anchoring the distal portion of the catheter device to maintain the distal portion in the disc; and
introducing at least one substance into the disc through the catheter device.
2. A method as in claim 1, wherein positioning the distal portion comprises passing the catheter device through a lumen of an introducer device.
3. A method as in claim 2, wherein positioning the catheter device comprises:
passing the catheter device through the lumen of the introducer device over a pointed stylet;
piercing through an annulus fibrosis of the disc using the stylet; and
withdrawing the stylet from the catheter device.
4. A method as in claim 2, wherein positioning the distal portion further comprises piercing through an annulus fibrosis of the disc with a tapered distal end of the catheter device.
5. A method as in claim 4, wherein positioning the distal portion further comprises passing the catheter device over a guidewire.
6. A method as in claim 2, wherein a distal end of the introducer device is advanced to a position in the disc before the catheter device is passed through the introducer device .

7. A method as in claim 6, wherein positioning the distal portion further comprises passing the catheter device over a guidewire.

8. A method as in claim 7, wherein the catheter device is passed through the introducer device over a guidewire.

9. A method as in claim 7, wherein the introducer device is removed over the guidewire before the catheter device is passed over the guidewire.

10. A method as in claim 1, wherein positioning the distal portion comprises visualizing at least one radiopaque marker or material at or near the distal portion to assess the location of the distal portion.

11. A method as in claim 1, wherein anchoring comprises deploying at least one anchoring member of the catheter device.

12. A method as in claim 11, wherein the at least one anchoring member is deployed on or near the distal portion of the catheter device.

13. A method as in claim 12, wherein anchoring comprises inflating at least a first expandable member in the disc.

14. A method as in claim 13, further comprising inflating at least a second expandable member adjacent an outer surface of the disc.

15. A method as in claim 1, wherein anchoring comprises deploying at least one mechanism on or near the distal portion of the catheter device to increase the effective cross-sectional diameter of the catheter at one or more locations.

16. A method as in claim 15, wherein increasing the cross-sectional diameter comprises releasing one or more shape memory or spring loaded members from constraint.

17. A method as in claim 15, wherein increasing the cross-sectional diameter comprises actuating one or more mechanical members of the catheter.

18. A method as in claim 15, wherein increasing the cross-sectional diameter comprises moving an inner catheter shaft of the catheter device relative to an outer

catheter shaft of the catheter device to cause one or more anchoring members to buckle outwards.

19. A method as in claim 1, wherein anchoring comprises causing at least part of the distal portion to change from a substantially straight shape to a substantially curved or geometric shape.

20. A method as in claim 1, wherein anchoring comprises attaching part of the distal portion to an annulus fibrosis of the disc.

21. A method as in claim 20, wherein attaching part of the distal portion to the annulus fibrosis comprises at least one of screwing, twisting and piercing the part of the attachment member into the annulus fibrosis.

22. A method as in claim 1, wherein introducing the at least one substance comprises introducing at least one of an anesthetic; an analgesic; an antibiotic; a hydrating agent such as hypotonic saline, isotonic saline or hypertonic saline; a supportive agent such as a hydrogel, ethylene-vinyl alcohol copolymer, Dimethyl Sulfoxide or Tantalum; a prolotherapy agent such as sodium morrhuate, cod oil, phenol, minerals or ethyl alcohol; and other agents such as collagen, stem cells, Osteogenic Protein-1, ethanol, alcohol, steroids, radio-opaque contrast agents, ultrasound contrast agent, Bone Morphogenetic Protein (BMP), BMP-2, BMP-4, BMP-6, BMP-7, BMP-12, Serotonin 5-HT_{2A} receptor inhibitors, LMP-1, TIMP-1, TGF-1, TGF-2, Rofecoxib, Ketorolac, Glucosamine, Chondroitin Sulfate, Dextrose, DMSO, non-steroidal antiinflammatory drugs, ibuprofen, naprosyn, Bextra, Vioxx, Celebrex, indomethacin, botulinum toxin, capsaicin, vanilloid agonists, vanilloid antagonists, VR1, VRL-1, steroids, methylprednisolone or chymopapain.

23. A method as in claim 22, wherein at least two different substances are introduced into the disc.

24. A method as in claim 1, wherein introducing the at least one substance comprises introducing a placebo substance into the disc.

25. A method as in claim 1, further comprising, before introducing the at least one substance, causing the patient to assume a position in which substantial spinal pain

is experienced, wherein the at least one substance includes at least one anesthetic or analgesic.

26. A method as in claim 25, further comprising:
positioning a distal portion of a second catheter device in a second intervertebral disc;
anchoring the distal portion of the second catheter device to maintain the distal portion in the second disc; and
introducing at least one substance into the second disc through the second catheter device.

27. A method as in claim 26, further comprising, before introducing the at least one substance into the second disc, causing the patient to assume a position in which substantial spinal pain is experienced, wherein the at least one substance includes at least one anesthetic or analgesic.

28. A method as in claim 27, further comprising determining which of the discs into which the at least one substance was introduced is causing the patient's spinal pain.

29. A method as in claim 25, further comprising performing a discography procedure on the intervertebral disc before positioning the distal portion of the catheter device in the disc.

30. A method as in claim 25, further comprising performing a discography procedure on the intervertebral disc after introducing the at least one anesthetic or analgesic.

31. A method as in claim 1, wherein the at least one substance is introduced automatically over a period of time.

32. A method as in claim 31, further comprising recording one or more patient inputs describing back pain experienced by the patient.

33. A method as in claim 1, further comprising:
leaving the catheter device in position with the distal portion in the disc; and
administering the at least one substance over time to provide treatment of spinal pain.

34. A method as in claim 33, wherein at least one substance is administered over time via a subcutaneous injection port or implanted pump, the method further comprising coupling the catheter device to the subcutaneous injection port or implanted pump.

35. A method for identifying an intervertebral disc that is causing pain, the method comprising:

- positioning a distal portion of a catheter device in a disc of a patient;
- anchoring the distal portion of the catheter device to maintain the distal portion in the disc;
- causing the patient to assume a position in which substantial spinal pain is experienced; and
- introducing at least one substance into the disc through the catheter.

36. A method as in claim 35, wherein positioning the distal portion comprises passing the catheter device through a lumen of an introducer device.

37. A method as in claim 36, wherein positioning the catheter device comprises:

- passing the catheter device through the lumen of the introducer device over a pointed stylet;
- piercing through an annulus fibrosis of the disc using the stylet; and
- withdrawing the stylet from the catheter device.

38. A method as in claim 36, wherein positioning the distal portion further comprises piercing through the annulus fibrosis into the disc with a tapered distal end of the catheter device.

39. A method as in claim 38, wherein positioning the distal portion further comprises passing the catheter device over a guidewire.

40. A method as in claim 36, wherein a distal end of the introducer device is advanced to a position within the disc before the catheter device is passed through the introducer device .

41. A method as in claim 40, wherein positioning the distal portion further comprises passing the catheter device over a guidewire.

42. A method as in claim 41, wherein the catheter device is passed through the introducer device over a guidewire.

43. A method as in claim 41, wherein the introducer device is removed over the guidewire before the catheter device is passed over the guidewire.

44. A method as in claim 35, wherein positioning the distal portion comprises visualizing at least one radiopaque marker or material at or near the distal portion to assess the location of the distal portion.

45. A method as in claim 35, wherein anchoring comprises deploying at least one anchoring member of the catheter device.

46. A method as in claim 45, wherein the at least one anchoring member is deployed on or near the distal portion of the catheter device.

47. A method as in claim 46, wherein anchoring comprises inflating at least a first expandable member in the disc.

48. A method as in claim 47, further comprising inflating at least a second expandable member adjacent an outer surface of the disc.

49. A method as in claim 35, wherein anchoring comprises deploying at least one mechanism along the distal portion of the catheter device to increase the effective cross-sectional diameter of the catheter at one or more locations.

50. A method as in claim 35, wherein anchoring comprises causing at least part of the distal portion to change from a substantially straight shape to a substantially curved or geometric shape.

51. A method as in claim 35, wherein anchoring comprises attaching part of the distal portion to an annulus fibrosis of the disc.

52. A method as in claim 35, wherein introducing the at least one substance comprises introducing at least one of an anesthetic; an analgesic; an antibiotic; a hydrating agent such as hypotonic saline, isotonic saline or hypertonic saline; a supportive agent such as a hydrogel, ethylene-vinyl alcohol copolymer, Dimethyl Sulfoxide or Tantalum; a prolotherapy agent such as sodium morrhuate, cod oil, phenol, minerals or ethyl alcohol; and other agents such as collagen, stem cells, Osteogenic Protein-1, ethanol, alcohol, steroids, radio-opaque contrast agents, ultrasound contrast agent, Bone Morphogenetic Protein (BMP), BMP-2, BMP-4, BMP-6, BMP-7, BMP-12, Serotonin 5-HT2A receptor inhibitors, LMP-1, TIMP-1, TGF-1, TGF-2, Rofecoxib, Ketorolac, Glucosamine, Chondroitin Sulfate, Dextrose, DMSO, non-steroidal antiinflammatory drugs, ibuprofen, naprosyn, Bextra, Vioxx, Celebrex, indomethacin, botulinum toxin, capsaicin, vanilloid agonists, vanilloid antagonists, VR1, VRL-1, steroids, methylprednisolone or chymopapain.

53. A method as in claim 35, wherein introducing the at least one substance comprises introducing a placebo substance into the disc.

54. A method as in claim 35, wherein introducing the at least one substance substantially reduces the spinal pain.

55. A method as in claim 35, wherein introducing the at least one substance does not substantially reduce the spinal pain.

56. A method as in claim 35, further comprising:
positioning a distal portion of a second catheter device in a second intervertebral disc;
anchoring the distal portion of the second catheter device to maintain the distal portion in the second disc; and
introducing at least one substance into the second disc through the second catheter device.

57. A method as in claim 56, further comprising, before introducing the at least one substance into the second disc, causing the patient to assume a position in which substantial spinal pain is experienced, wherein the at least one substance includes at least one anesthetic or analgesic.

58. A method as in claim 57, further comprising determining which of the discs into which the at least one substance was introduced is causing the patient's spinal pain.

59. A method as in claim 35, further comprising performing a discography procedure on the intervertebral disc.

60. A method as in claim 35, further comprising:
leaving the catheter device in position with the distal portion in the disc; and
administering the at least one substance over time to provide treatment of spinal pain.

61. A method as in claim 60, wherein at least one substance is administered over time via a subcutaneous injection port or implanted pump, the method further comprising coupling the catheter device to the subcutaneous injection port or implanted pump.

62. A method as in claim 35, wherein the at least one substance is introduced automatically over a period of time.

63. A method as in claim 63, further comprising recording one or more patient inputs describing back pain experienced by the patient.

64. A catheter device for introducing one or more substances into an intervertebral disc, the device comprising:
an elongate flexible catheter body having a proximal portion, a self-introducing distal portion for facilitating penetration of an annulus fibrosis of the disc, and at least one lumen for introducing one or more substances into the intervertebral disc; and
at least one anchoring member disposed along the catheter body for anchoring at least part of the distal portion of the catheter in the intervertebral disc.

65. A device as in claim 64, wherein the at least one anchoring member is disposed along the catheter body at or near the distal portion.

66. A device as in claim 64, wherein the at least one anchoring member comprises at least one expandable member coupled with an inflation lumen.

67. A device as in claim 64, wherein the at least one anchoring member comprises at least one shape memory, spring loaded or mechanically activated member for increasing the effective cross-sectional diameter of the catheter body at or near the distal portion.

68. A device as in claim 64, wherein the at least one anchoring member comprises at least one outwardly buckling member coupled with an inner catheter shaft and an outer catheter shaft of the catheter body so as to outwardly buckle when the inner shaft is moved axially relative to the outer shaft.

69. A device as in claim 64, wherein the at least one anchoring member comprises at least one attachment member for attaching to an annulus fibrosis of the disc.

70. A device as in claim 69, wherein the attachment member comprises at least one threaded surface.

71. A device as in claim 69, wherein the attachment member comprises at least one spiral needle.

72. A device as in claim 64, wherein the at least one anchoring member comprises at least one deformable member to change at least part of the distal portion from a substantially straight shape to a substantially curved or geometric shape.

73. A device as in claim 64, wherein the self-introducing distal portion comprises at least one pushable portion, the pushable portion having a stiffness greater than adjacent portions of the catheter body.

74. A device as in claim 73, wherein the self-introducing portion further comprises a tapered distal end of the catheter device.

75. A device as in claim 64, further comprising a pointed stylet removably disposed within a lumen of the catheter device for piercing through the annulus fibrosis of the disc.

76. A device as in claim 64, wherein the catheter body comprises a friction resistant outer surface.

77. A device as in claim 64, wherein an outer diameter of the catheter body is less than 2 mm.

78. A device as in claim 64, wherein a cross-sectional diameter of the catheter body decreases along its length from a proximal end to a distal end.

79. A device as in claim 64, wherein the catheter body comprises an outer surface having one or more markings for indicating depth of insertion of the catheter device into a patient's body.

80. A device as in claim 64, wherein the catheter body comprises an outer surface having two or more different colors for indicating depth of insertion of the catheter device into a patient's body.

81. A device as in claim 64, wherein the catheter body comprises at least one radiopaque marker or material for facilitating visualization of the catheter device in a patient.

82. A device as in claim 64, further comprising:
an injection tube extending through at least part of the lumen of the catheter body for introducing one or more substances into the disc; and
an inflation tube extending through at least part of the lumen for expanding the deployable anchoring member.

83. A device as in claim 82, wherein the injection tube comprises a material selected from the group consisting of stainless steel, tempered stainless steel, annealed stainless steel, polymers, and superelastic alloys.

84. A device as in claim 82, wherein the injection and inflation tubes exit a proximal end of the catheter body and are removably coupled with at least one adapter to provide for injection and inflation.

85. A device as in claim 82, wherein the injection and inflation tubes extend through at least part of the catheter body lumen coaxially.

86. A device as in claim 82, wherein the injection and inflation tubes extend through at least part of the catheter body lumen side-by-side.

87. A device as in claim 82, wherein the injection and inflation tubes extend through part of the catheter body lumen coaxially and through another part of the lumen side-by-side.

88. A device as in claim 64, wherein a proximal end of the proximal portion of the catheter body is bifurcated into two separate catheter body proximal ends.

89. A device as in claim 88, wherein each of the two proximal ends is removably coupled with an adapter for facilitating injection or inflation via either end.

90. A device as in claim 64, further comprising a guidewire having a distal end shaped to maintain the distal end within the disc.

91. A device as in claim 90, wherein the distal end comprises at least one of a double-wire guidewire, a coil and a pigtail.

92. A system for introducing one or more substances into an intervertebral disc, the system comprising:

an introducer device; and

a catheter device passable through the introducer device, the catheter device comprising:

an elongate flexible catheter body having a proximal portion, a self-introducing distal portion for facilitating penetration of an annulus fibrosis of the disc, and at least one lumen for introducing one or more substances into the intervertebral disc; and

at least one anchoring member disposed along the catheter body for anchoring at least part of the distal portion of the catheter in the disc.

93. A system as in claim 92, further comprising a pointed stylet removably disposed within a lumen of the catheter device for piercing through the annulus fibrosis.

94. A system as in claim 92, further comprising a guidewire over which the catheter device may be passed within the needle.

95. A system as in claim 92, wherein the at least one anchoring member is disposed along the catheter body at or near the distal end.

96. A system as in claim 92, wherein the at least one anchoring member comprises at least one expandable member.

97. A system as in claim 92, wherein the at least one anchoring member comprises at least one shape memory, spring loaded or mechanically activated member for increasing the effective cross-sectional diameter of the catheter body at or near the distal portion.

98. A system as in claim 92, wherein the at least one anchoring member comprises at least one outwardly buckling member coupled with an inner catheter shaft and an outer catheter shaft of the catheter body so as to outwardly buckle when the inner shaft is moved axially relative to the outer shaft.

99. A system as in claim 92, wherein the at least one anchoring member comprises at least one attachment member for attaching to an annulus fibrosis of the disc.

100. A system as in claim 99, wherein the attachment member comprises at least one threaded surface.

101. A system as in claim 99, wherein the attachment member comprises at least one spiral needle.

102. A system as in claim 92, wherein the at least one anchoring member comprises at least one deformable member to change at least part of the distal portion from a substantially straight shape to a substantially curved or geometric shape.

103. A device as in claim 92, wherein the self-introducing distal portion comprises at least one pushable portion, the pushable portion having a stiffness greater than adjacent portions of the catheter body.

104. (currently amended) A device as in claim ~~104~~ 103, wherein the self-introducing portion further comprises a tapered distal end of the catheter device.

105. A system as in claim 92, wherein the catheter body comprises a friction resistant outer surface.

106. A system as in claim 92, wherein an outer diameter of the catheter body is less than 2 mm.

107. A system as in claim 106, wherein an inner diameter of the needle is between about 0.1 mm and about 0.01 mm larger than the outer diameter of the catheter body.

108. A system as in claim 92, wherein the catheter body comprises an outer surface having one or more markings for indicating depth of insertion of the catheter device into a patient's body.

109. A system as in claim 92, wherein the catheter body comprises an outer surface having two or more different colors for indicating depth of insertion of the catheter device into a patient's body.

110. A system as in claim 92, wherein the catheter body comprises at least one radiopaque marker or material for facilitating visualization of the catheter device in a patient.

111. A system as in claim 92, further comprising:
an injection tube extending through at least part of the lumen of the catheter body for introducing one or more substances into the disc; and
an inflation tube extending through at least part of the lumen for expanding the deployable anchoring member.

112. A system as in claim 111, wherein the injection lumen comprises a material selected from the group consisting of stainless steel, tempered stainless steel, annealed stainless steel, polymers, and superelastic alloys.

113. A system as in claim 111, wherein the injection and inflation tubes exit a proximal end of the catheter body and are removably coupled with two separate adapters for facilitating injection and inflation, respectively.

114. A system as in claim 111, wherein the injection and inflation tubes extend through at least part of the catheter body lumen coaxially.

115. A system as in claim 111, wherein the injection and inflation tubes extend through at least part of the catheter body lumen side-by-side.

116. A system as in claim 111, wherein the injection and inflation tubes extend through part of the catheter body lumen coaxially and through another part of the lumen side-by-side.

117. A system as in claim 92, wherein a proximal end of the proximal portion of the catheter body is bifurcated into two separate catheter body proximal ends.

118. A system as in claim 117, wherein each of the two proximal ends is coupled with removably coupled with an adapter for facilitating injection or inflation via either end.

119. A system as in claim 92, wherein the guidewire comprises a curved tip for maintaining a distal portion of the guidewire within the disc.

120. A system as in claim 92, wherein the guidewire comprises at least one attachment member for attaching to an annulus fibrosis of the intervertebral disc to maintain a distal portion of the guidewire within the disc.

121. A system as in claim 92, further comprising an implantable pump for coupling with the catheter device for introducing one or more substances into the disc over time.

122. A system as in claim 92, further comprising an implantable injection port for coupling with the catheter device for introducing one or more substances into the disc over time.

123. A system as in claim 92, further comprising an automatic injection device removably coupled with the catheter device for automatically introducing the at least one substance into the disc.

124. A system as in claim 123, further comprising a recording device for recording patient inputs describing pain felt by a patient.

125. A kit for introducing one or more substances into an intervertebral disc, the kit comprising:

a catheter device comprising:

an elongate flexible catheter body having a proximal portion, a self-introducing distal portion for facilitating penetration of an annulus fibrosis of the disc, and at least one lumen for introducing one or more substances into the intervertebral disc; and

at least one anchoring member disposed along the catheter body at or near the distal portion for anchoring at least part of the distal portion of the catheter in the disc;

at least one implantable device removably couplable with the catheter device for introducing the one or more substances into the disc over time; and

instructions for using the catheter device and implantable device.

126. A kit as in claim 125, wherein the implantable device comprises a pump.

127. A kit as in claim 125, wherein the implantable device comprises an injection port.

128. A kit as in claim 125, further comprising an introducer device for facilitating positioning of the catheter device in the disc.

129. A kit as in claim 128, further comprising a pointed stylet removably disposed within a lumen of the catheter device for piercing through the annulus fibrosis.

130. A kit as in claim 128, further comprising a guidewire passable through the needle.